

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pantoprazole Nycomed i.v. 40 mg powder for solution for injection Pantoprazole

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Pantoprazole Nycomed is and what it is used for
2. Before you use Pantoprazole Nycomed
3. How to use Pantoprazole Nycomed
4. Possible side effects
5. How to store Pantoprazole Nycomed
6. Further information

1. WHAT PANTOPRAZOLE NYCOMED IS AND WHAT IT IS USED FOR

Pantoprazole Nycomed is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related disease of the stomach and intestine. This preparation is injected into a vein and will only be given to you if your doctor thinks pantoprazole injections are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections as soon as your doctor sees fit.

Pantoprazole Nycomed is used for treating:

- Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitating of stomach acid.
- Stomach and duodenal ulcers
- Zollinger-Ellison Syndrome and other conditions producing too much acid in the stomach.

2. BEFORE YOU USE PANTOPRAZOLE NYCOMED

Do not use Pantoprazole Nycomed

- If you are allergic (hypersensitive) to pantoprazole or any of the other ingredients of Pantoprazole Nycomed (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Take special care with Pantoprazole Nycomed

- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently. In the case of a rise of liver enzymes the treatment should be stopped.
- If you are taking a medicine containing atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional loss of weight
- repeated vomiting
- difficulty in swallowing
- vomiting blood
- you look pale and feel weak (anaemia)
- you notice blood in your stools
- severe and/or persistent diarrhoea, as Pantoprazole Nycomed has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

Taking other medicines

- Pantoprazole Nycomed injections may influence the effectiveness of other medicines, so tell your doctor if you are taking
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole Nycomed may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening or thinning of the blood. You may need further checks.

Atazanavir (used to treat HIV-infection).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. If you are pregnant, or think you may be pregnant, or if you are breast-feeding, you should use this medicine, only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Important information about some of the ingredients of Pantoprazole Nycomed

This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. is essentially 'sodium-free'.

3. HOW TO USE PANTOPRAZOLE NYCOMED

Your nurse or your doctor will administer the daily dose to you as an injection into a vein over a period of 2-15 minutes.

The usual dose is:

For gastric ulcers, duodenal ulcers and reflux oesophagitis:

One vial (40 mg pantoprazole) a day.

For the treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced:

Two vials (80 mg pantoprazole) a day

Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If you are prescribed more than two vials (80 mg) a day, the injections will be given in two equal doses. Your doctor may prescribe a temporary dose of more than four vials (160 mg) a day. If your stomach acid level needs to be controlled rapidly, a starting dose of 160 mg (four vials) should be enough to lower amount of stomach acid sufficiently.

Special patient groups:

- If you suffer from severe liver problems, the daily injection should be only 20 mg (half a vial).
- Children (under 18 years). These injections are not recommended for use in children.

If you use more Pantoprazole Nycomed than you should

These doses are carefully checked by your nurse or your doctor so an overdose is extremely unlikely. There are no known symptoms of overdose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pantoprazole Nycomed can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10, 000)

very rare (affects less than 1 user in 10, 000)

not known (frequency cannot be estimated from the available data)

If you get any of the following side effects, tell your doctor immediately, or contact the casualty department at your nearest hospital:

- **Serious allergic reactions (frequency rare):** swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin conditions (frequency not known):** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, Erythema multiforme) and sensitivity to light.
- **Other serious conditions (frequency not known):** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

Other known side effects are:

- **Common** (affects 1 to 10 users in 100)
inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected

- **Uncommon** (affects 1 to 10 users in 1,000)
headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence;(wind) constipation; dry mouth; abdominal pain and discomfort; skin rash, exanthema, eruption; itching; feeling weak, exhausted or generally unwell; sleep disorders.
Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- **Rare** (affects 1 to 10 users in 10,000)
Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature;high fever, swelling of the extremities (peripheral oedema); allergic reactions; depression, breast enlargement in males.
- **Very Rare** (affects less than 1 user in 10,000)
disorientation.
- **Not Known** (frequency cannot be stimated from the available data)
Hallucination, confusion (especially in patients with a history of these symptoms), decreased sodium level in blood.
If you are on Pantoprazole Nycomed for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Side effects identified through blood tests:

- **Uncommon** (affects 1 to 10 users in users in 1,000)
an increase in liver enzymes
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- **Rare** (affects 1 to 10 users in 10,000)
an increase in bilirubin; increased fat levels in blood
- **Very Rare** (affects less than 1 user in 10,000)
a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PANTOPRAZOLE NYCOMED

Keep out of the reach and sight of children.

Do not use Pantoprazole Nycomed after the expiry date, which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the vial in the outer carton in order to protect it from

Use the reconstituted solution within 12 hours.

Use the reconstituted and diluted solution within 12 hours.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at not more than 25 °C.

Do not use Pantoprazole Nycomed if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Pantoprazole Nycomed contains

- The active substance is pantoprazole. Each vial contains 40 mg of pantoprazole (as sodium sequihydrate)
- The other ingredients are: disodium edetate, sodium hydroxide (for pH adjustment).

What Pantoprazole Nycomed looks like and contents of the pack

Pantoprazole Nycomed is a white to off-white powder for solution for injection. It comes in a 10 ml clear glass vial closed with an aluminium cap and grey rubber stopper containing 40 mg powder for solution for injection.

Pantoprazole Nycomed is available in the following pack sizes:

Packs with 1, 5 (5x1) vials

Hospital packs with 1, 5 (5x1), 10 (10x1), 20 (20x1) vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Takeda GmbH
Byk-Gulden-Straße 2
D-78467 Konstanz
Germany

Manufacturer

Takeda GmbH
Production site Singen
Robert-Bosch-Straße 8
D-78224 Singen
Germany

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The following information is intended for medical or healthcare professionals only:

A ready-to-use solution is prepared by injecting 10 ml of sodium chloride 9 mg/ml (0.9%) solution for injection into the vial containing the dry powder. This solution may either be administered directly or after

mixing with 100 ml physiological sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 55 mg/ml (5%) solution for injection. Glass or plastic containers should be used for dilution.

Pantoprazole should not be prepared or mixed with solvents other than those stated.

After preparation, the solution must be used within 12 hours. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours, at no more than 25 °C.

The medicinal product should be administered intravenously over 2 - 15 minutes.

The content of the vial is for single intravenous use only. Any product that has remained in the container or whose visual appearance has changed (e.g. if cloudiness or precipitation is observed) must be discarded.